PATENT

Attorney Docket No.: ZIEL 100-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Jan E. Zielinski	Art Unit:	1626
Application No.:	09/890,479	Examiner:	S. Wright
Filing Date:	February 8, 2002		
Title:	HESPERITIN PRO-FORMS WITH ENHANCED BIOAVAILABILITY		

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Requirement for Restriction dated January 14, 2003, Applicant elects, with traverse, Group I, consisting of Claims 1-5, drawn to hesperitin compounds.

It is alleged in the Office Action that the claims are directed to five inventions which are not so linked as to form a single general inventive concept. The alleged five groups are set out as follows:

Group I: Claims 1 through 5, drawn to hesperitin compounds.

Group II: Claims 6 through 12, drawn to a method of treating cell proliferative disorders with a hesperitin compound.

Group III: Claims 13, 14, and 16, drawn to a method of treating an oxidative stress disorder with a hesperitin compound.

CERTIFICATION UNDER 37 CFR §1.8
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, **January 30, 2003**, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.
Cara Grifone *(Name of Person Mailing Paper)*
Cara Grifone *(Signature)* — **January 30, 2003** *(Date)*

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Group IV: Claim 15, drawn to a method of treating a increased gland activity disorder with a hesperitin compound.

Group V: Claims 17 and 18, drawn to a method of treating a cardiovascular disorder with a hesperitin compound.

Although Applicants traverse the restriction requirement for the reasons set forth below, the claims of Group I, claims 1 through 5, are provisionally elected in order to be fully responsive to the Office Action.

The division of the claims set forth in Groups II, III, IV and V is respectfully traversed. As provided in MPEP §803, a proper restriction requirement is made where the inventions are independent (MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (MPEP § 806.05 - § 806.05(i)); and there is a serious burden on the Examiner (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). However, even if the species are viewed as independent or distinct, the claimed subject matter in each group is related by a "commonality of operation, function and effect" (see MPEP § 806.04(e)), such that election of a single species is improper. Additionally, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

The Applicants respectfully submit that the claims set forth in Groups II through V are not independent and distinct inventions. Specifically, the claims of Groups II through V are all directed at methods of use, particularly in treating a disorder with hesperitin compounds. Disorders included in the specification and referenced by the claims of Groups II through V include, without limitation, disorders associated with cell proliferation, oxidative stress, gland activity, and cardiovascular disorders. Although the claims differ with respect to the particular disorder treated, the similar methods of use in the claims of Groups II through V do not constitute separate and distinct inventions and should be examined together.

The Applicants further submit that while the claims of Groups II through V differ with respect to the particular disorder treated, the specification discloses that the methods of use are related by a commonality of operation, function or effect. Specifically, effective inhibition of 3-hydroxy-3-methylglutaryl CoA by hesperidin and hesperetin is discussed on page 2 of the application. It is known that 3-hydroxy-3-methylglutaryl CoA inhibition has a variety of beneficial pleiotropic effects. Treatment with 3-hydroxy-3-methylglutaryl CoA inhibitors reduces levels of low-density lipoproteins, raises high-density lipoproteins, and lowers triglycerides, thus reducing the risk of cardiovascular disorders. Other examples of pleiotropic effects include alterations of endothelial function, inflammation, coagulation and plaque stability. In addition, 3-hydroxy-3-methylglutaryl CoA inhibitors interfere with events involved in bone formation, oxidative stress and impede tumor cell growth. The claims set forth in Groups II through V are similar methods of use that embrace a variety of effects, while operating in the same manner. It is submitted that the claims of Groups II through V possess commonality of operation, function and effect in that the methods of use involve inhibition of 3-hydroxy-3-methylglutaryl CoA. Therefore, it would not place an undue burden on the Examiner to search various disorders treated by the administration of hesperetin compounds and it is respectfully requested that the restriction requirement be reconsidered and withdrawn.

The restriction requirement is also traversed with respect to Group I, which is directed to hesperitin compounds, and Groups II, III, IV and V, which are directed to methods of treating disorders by administration of hesperitin compounds. Even if the claims of Group I are independent and patentably distinct from the claims of Groups II - V, Applicants submit that the subject matter of Groups I through V are so closely related that division of the claims into separate groups would result in duplication of effort by the U.S. Patent and Trademark Office. Specifically, the claims of Group I would require a search of hesperitin compounds, as well as methods of using such compounds. Likewise, the claims of Group II through V also require a search for hesperitin compounds and methods of use thereof, particularly methods of using

hesperitin compounds in the treatment of various medical conditions. Accordingly, a search of the claims of elected Group I would include art relevant to hesperitin compounds and their methods of use and, therefore, relevant to examination of the claims of Groups II through V. For the reasons stated, it is respectfully requested that the Examiner reconsider and remove the restriction requirement with respect to the claims of Group I and Groups II through V, and examine these claims together.

In summary, Applicants provisionally elect the claims set forth in Group I for examination. However, for the reasons specified above, it is respectfully requested that the claims of Groups I, II, III, IV, and V be rejoined and examined together.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: 1/30/03

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